Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs

Syfovre™ (pegcetacoplan injection)

Effective: July 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Syfovre was based on two Phase 3 trials, DERBY and OAKS, that evaluated the efficacy of Syfovre administered via intravitreal injection monthly or every other month (EOM), compared with sham injections for the treatment of GA secondary to AMD. Reductions in geographic lesion growth ranged from 17 to 22% from baseline to Month 24. Syfovre did not meet the primary outcome of change in lesion growth compared to sham at 12 months in the DERBY trial. There was no difference between Syfovre and sham in outcomes measuring visual function at 24 months. In the DERBY and OAKS clinical trials, Syfovre-treated patients experienced a higher rate of new-onset neovascular AMD (nAMD) (also known as wet AMD [wAMD]): 12%, 7%, and 3% in the Syfovre monthly, EOM, and sham groups, respectively, at 24 months, based on pooled data.

Food and Drug Administration (FDA) Approved Indications:

Syfovre (pegcetacoplan) is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Syfovre for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of geographic atrophy secondary to age-related macular degeneration

AND

2. Prescribed by or in consultation with an ophthalmologist

Reauthorization Criteria

1. Documented diagnosis of geographic atrophy secondary to age-related macular degeneration

AND

2. Prescribed by or in consultation with an ophthalmologist

AND

3. Documentation the patient is responding positively to therapy (e.g., disease stabilization or slowing of the rate of disease progression compared to pre-treatment baseline)

Limitations

- Syfovre will be authorized for in 12-month intervals.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2781	Injection, pegcetacoplan, 1 mg

References:

1. Flaxel CJ, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020;127(1):P1-65.
2. Syfovre (pegcetacoplan injection) [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; November 2023.

Approval And Revision History

July 11, 2023: Reviewed by the Pharmacy & Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- Updated description of HCPC code: October 1, 2023: Administrative update: Updated description of J code J2781 to Medical Necessity Guideline.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- May 14, 2024: No changes (eff 7/1/24).
- June 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/24).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.